UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,670	12/19/2005	Franco Macchi	207,380	5848

7590 03/28/2008

Jay S Cinamon
Abelman Frayne & Schwab
10th floor
666 Third Avenue
New York, NY 10017

EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,670	MACCHI, FRANCO	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to Applicant's amendment submitted February 4, 2008, wherein claims 7-12 are amended. Claims 7-12 are currently pending and are examined on the merits herein.

In view of Applicant's amendment submitted February 4, 2008, the objection to claim 10 for informalities is withdrawn. However, it is noted that "s" which was added to the word "composition" at the end of claim 10 is not underlined to indicate the amendment.

In view of Applicant's amendment submitted February 4, 2008, the rejection of claims 8-12 under 35 USC 112, second paragraph, for being dependent on claims which are cancelled, is withdrawn.

In view of Applicant's amendment submitted February 4, 2008, the rejection of claims 8-11 under 35 USC 112, second paragraph, for lacking antecedent basis, is withdrawn.

In view of Applicant's amendment submitted February 4, 2008, the rejection of claims 7-12 under 35 USC 102(b) as being anticipated by Di Schiena, is withdrawn. Di Schiena does not exemplify treatment of ROAU and thus the claims are not anticipated.

Claim Objections

Claim 11 is objected to because of the following informalities: "4" is still present in claim 11, and was apparently intended to be deleted from the claim. Appropriate correction is required.

The following rejection of record is maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of oral cavity aphthas, does not reasonably provide enablement for the prevention of such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on

the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method for the prevention or treatment of oral cavity aphthas comprising administering hyaluronic acid. Stedman's Medical Dictionary 27th Edition defines "aphtha" as a small ulcer on a mucous membrane. Thus, the claims taken together with the specification imply that the administration of hyaluronic acid can prevent ulcer formation on oral mucous membranes.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The Merck Manual Home Edition states that there are many types and causes of mouth sores. Any type of damage to the mouth, including poor-fitting dentures and jagged teeth, can cause ulcers to form in the mouth. Many foods can be irritating and cause an allergic reaction, causing mouth sores. Viruses are a common cause of

mouth sores. Canker sores are a common type of mouth sore, and their cause is unknown.

Given the wide variety of factors which can cause mouth sores, many of which are unknown, one skilled in the art would not reasonably expect a single composition to prevent all such occurrences.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the treatment of patients who have an current ulcer.

However, the specification does not provide guidance for the prevention of ulcer formation. Patients who did not have a current ulcer were asked to contact the clinic at the onset of their next ulcer.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the many causes of mouth sores and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Response to Arguments

Applicant's arguments filed February 4, 2008 have been fully considered but they are not persuasive.

Applicant argues that, when compared to a placebo, administration of the HA composition was able to reduce the number of ulcers, which means that HA inhibited the formation of new ulcers. Applicant indicates that data is available which shows that patients treated with HA have lesser recurrence of ulcers than patients treated with placebo.

The meaning of terms in a claim are given their broadest reasonable interpretation. Thus, the word "prevention" is interpreted as absolute prevention. In the response dated February 4, 2008, applicant states that 29 patients treated with HA had new ulcers in a 7 day investigation period. Clearly, this is not absolute prevention.

The following is a new rejection necessitated by Applicant's amendment, which changed the scope of the claims such that one disorder, ROAU, is treated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Schiena (EP 0444492, April 9, 1991, PTO-1449 submitted May 3, 2007) in view of Saxen et al. (Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1997; 84:356-61).

Di Schiena teaches pharmaceutical compositions comprising 0.2 to 10% sodium hyaluronate having molecular weight between 800,000-4,000,000 for the treatment of oral stomatitis [claims 1-10].

Di Schiena does not exemplify the treatment of recurrent oral aphthous ulcers (recurrent aphthous stomatitis) using the composition.

Saxen et al. teach that recurrent aphthous ulcers are a common disorder and the most common treatment is topical anesthetics and topical steroids for pain management [page 356, first two paragraphs]. Saxen et al. teach a study in which adults having aphthous ulcers were treated with 3% diclofenac in 2.5% hyaluronan, 2.5% hyaluronan, or 3% viscous lidocaine. A reduction in pain was observed 10 minutes after application with no significant difference between the three topical agents [see abstract]. The blunting action of hyaluronan may be due to the coating action over the ulcer [page 360, second full paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat ROAU with the composition of Di Schiena. Di Schiena teaches the composition for the treatment of stomatitis in general, and the skilled artisan would expect such a composition to be useful for treatment of ROAU, a particular form of stomatitis. Furthermore, Saxen et al. teach that hyaluronan is effective for the treatment of recurrent aphthous ulcers. The claims are clearly obvious over the prior art.

Response to Arguments

Applicant's arguments with respect to the rejection of claims 7-12 as anticipated by De Schiena et al. have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that page 4, lines 10-12, of the office action mailed October 11, 2007, provides evidence that the claims are patentable over 35 USC 103(a). Applicant is presumably referring to the following statement: "Given the wide variety of factors which can cause mouth sores, many of which are unknown, one skilled in the art would not reasonably expect a single composition to prevent all such occurrences." This statement is part of a discussion on the lack of enablement for prevention of mouth sores. This statement is not an implicit acknowledgement by the examiner that the claims are patentable under 35 USC 103(a), and it is unclear how Applicant arrived at that conclusion. Thus, Applicant's argument is not persuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623